MITIGATION AND PREVENTION OF MEDICATION ERRORS IN PHARMACY PRACTICE

2024

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Learning Objectives

Upon completion of this program, the Pharmacist and Registered Pharmacy Technician shall be able to:

-Recognize statutory responsibilities that foster ongoing pharmacy regulatory compliance

-Describe quality improvement regulations for pharmacies licensed in Florida

-Recognize recurring medication errors

-Define elements of a proactive Continuous Quality Improvement process

-Discuss the use of Root Cause Analysis (RCA) to enhance quality pharmacy services and prevent errors

-Describe the implementation of an action plan to improve overall pharmacy practice quality and mitigate medication errors

-Demonstrate enactment of procedures that promote ongoing patient safety in pharmacy practice

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DISCLOSURE

- I, NORMAN TOMAKA, DO NOT HAVE A VESTED INTEREST OR AN AFFILIATION WITH ANY CORPORATION OR ORGANIZATION OFFERING FINANCIAL SUPPORT OR GRANT MONIES FOR THIS SEMINAR.
- I DO NOT HAVE AN AFFILIATION WITH ANY ORGANIZATION WHOSE PHILOSOPHY COULD POTENTIALLY BIAS THIS PRESENTATION.
- I DO NOT PRESENT THE FOLLOWING AS LEGAL ADVICE OR REGULATORY MANAGEMENT CONSULTATION.

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Norman P. Tomaka

- Pharmacist, Consultant Pharmacist
- BS Pharmacy- Duquesne University
- MS Pharmacy- University of Florida

- Health Care Risk Manager

- **Affiliations**
  - American Pharmacists Association
  - Brevard County Pharmacy Association
  - Florida Pharmacy Association
  - Florida Society of Health-System Pharmacists
  - Palm Beach County Pharmacy Association
  - Treasure Coast Society of Health-System Pharmacists
  - American Society of Consultant Pharmacists

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ACKNOWLEDGEMENT

ISMP Institute for Safe Medication Practices
An ECRI Affiliate

www.ismp.org

AHRQ Agency for Healthcare Research and Quality

www.ahrq.gov

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MSOS Forum

Mission: advance and encourage excellence in medication safety.

Provide communication, leadership, direction, and education.

Opportunity for information sharing and collaboration.

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ASSESSMENT QUESTIONS

IN FLORIDA, PHARMACISTS ARE REQUIRED TO DOCUMENT AND EVALUATE QUALITY RELATED EVENTS (**QRE.**) DESCRIBE A **QRE**

YOU HAVE JUST DOCUMENTED A **QRE**. CAN THIS DOCUMENT BE USED AGAINST YOU?

RECURRENT QUALITY RELATED EVENTS OFTEN INVOLVE **HIGH-RISK** DRUG PRODUCTS.
HOW CAN YOU DECIDE THE POTENTIAL FOR HIGH RISK AND ERROR?

QRE IS OFTEN PREVENTABLE IF PROCESS MANAGEMENT IS REVIEWED AND AN ACTION PLAN ENACTED. WHAT'S THE DIFFERENCE BETWEEN THE RCA AND FMEA?

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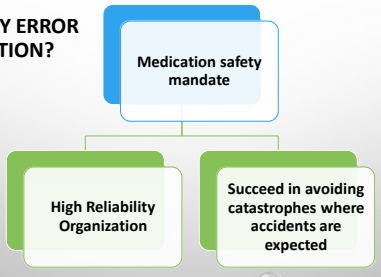
WHY STUDY ERROR PREVENTION?



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STATUTORY RESPONSIBILITY
FL PHARMACY QUALITY ASSURANCE

- CONDUCT AN ONGOING ANALYSIS OF QUALITY RELATED EVENTS (ERRORS)
- REVIEW EXTERNAL EVENTS
- REVIEW INTERNAL OCCURRENCES

- 64B16-27.300 STANDARDS OF PRACTICE
- CONTINUOUS QUALITY IMPROVEMENT PROCESS
- POLICY AND PROCEDURE FOR CQI COMMITTEE
  - DESCRIBE MEMBERS
  - COMPREHENSIVE PROCESS REVIEW
  - QUARTERLY DOCUMENTATION
  - MAINTAIN SUMMARIES FOR 48 MONTHS

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64B16-26.103 CONTINUING EDUCATION LICENSE RENEWAL

Prior to renewal a licensee must complete, within the 24 month period prior to the expiration date of the license, a **two-hour continuing education course** approved in advance by the Board on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety.

https://www.flrules.org/gateway/ruleno.asp?id=64B16-27.300

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FL Statutes: CQI

Continuous **Q**uality **I**mprovement

https://qualitysfo.com/achieving-excellence-through-continuous-quality-improvement/

Standards of Practice: system of standards and procedures to identify and evaluate quality-related events and improve patient care

Pharmacy must accumulate data and actively study errors (**Q**uality **R**elated **E**vent)

Error vs Good Catch **QRE**

Focus on prevention through active process

https://www.flrules.org/gateway/ruleno.asp?id=64B16-27.300

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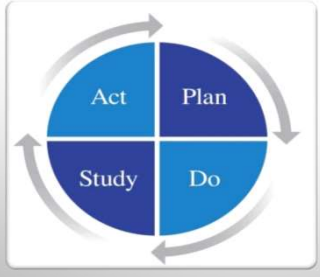

PLAN-DO-STUDY-ACT

- SYSTEMATIC PROCESS
- PURPOSE: GAINING KNOWLEDGE
- LEADS TO CONTINUAL IMPROVEMENT OF A PROCESS OR SERVICE

The Deming Institute. https://deming.org/explore/pdsa/

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QUALITY RELATED EVENT

QRE

Internal Event
Near Miss
"Good Catch"

Patient Level
Incorrect
Dispensing
Administration

- INAPPROPRIATE DISPENSING
- MIS-ADMINISTRATION OF A PRESCRIBED MEDICATION

"Fla. Admin. Code Ann. R. 64B16-27.300" Fla. Admin. Code R. 64B16-27.300

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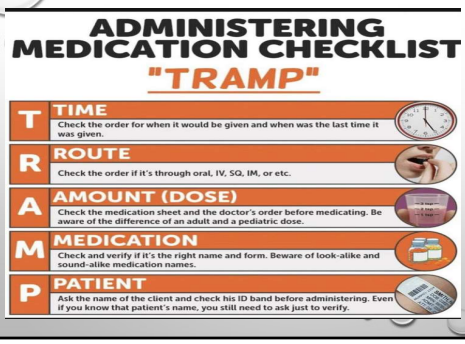
ADMINISTERING MEDICATION CHECKLIST "TRAMP"



ERROR POTENTIAL

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QUALITY RELATED EVENT

VARIATION FROM PRESCRIBER'S MEDICATION ORDER

- INCORRECT DRUG
- INCORRECT DRUG STRENGTH
- INCORRECT DOSAGE FORM
- INCORRECT PATIENT
- INADEQUATE DRUG PACKAGE/LABEL

FAILURE TO IDENTIFY AND MANAGE

- OVER/UNDER-UTILIZATION
- THERAPEUTIC DUPLICATION
- DRUG-DISEASE CONTRAINDICATIONS
- DRUG-DRUG INTERACTIONS
- INCORRECT DRUG DOSAGE
- INCORRECT DURATION OF TREATMENT
- DRUG-ALLERGY INTERACTIONS
- CLINICAL ABUSE/MISUSE

"Fla. Admin. Code Ann. R. 64B16-27.300" Fla. Admin. Code R. 64B16-27.300

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FL 64B16-27.300 **QRE** *VS* ≠ FL 65G-7.006 MEDICATION ERROR

- TERMS AND CONDITIONS TO BE FOLLOWED BY A PHARMACIST WHEN ORDERING AND DISPENSING APPROVED MEDICINAL DRUG PRODUCTS
- STANDARDS OF PRACTICE - CONTINUOUS QUALITY IMPROVEMENT PROGRAM REQUIREMENT

FL Department of Health, Board of Pharmacy, Pharmacy Practice
https://www.flrules.org/gateway/ruleno.asp?id=64B16-27.300

- AUTHORIZATION FOR MEDICATION ADMINISTRATION AND INFORMED CONSENT
- SELF-ADMINISTRATION OF MEDICATION WITHOUT SUPERVISION
- MEDICATION ADMINISTRATION TRAINER REQUIREMENTS, MEDICATION ADMINISTRATION

FL Dept. of Children and Families
https://www.flrules.org/gateway/RuleNo.asp?ID=65G-7.006

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CQI PROCESS
PLAN-DO-STUDY-ACT

- **PDSA**: Plan-Do-Study-Act (Deming cycle[1])
  Four-step process for quality improvement[2]
- **Plan** objectives and desired outcomes
- **Do** phase allows for plan implementation
- **Study/Check** phase gather data
- **Act** phase: Outcome achieved?

ACTION PLAN

Quality Related Event (**QRE**) requires process analysis that may lead to change/improvement.

Unique for each **QRE**

1. https://deming.org/explore/pdsa/
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3963536/

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PHARMACY CQI PROCESS
KEY ELEMENTS

- **ROOT CAUSE ANALYSIS (RCA)**
  - Why?
  - Reactive
- **FAILURE MODE EFFECTS ANALYSIS (FMEA)**
  - Risk mitigation
  - Proactive

ACTION PLAN

Quality Related Event (**QRE**) requires process analysis that may lead to changes

Unique for each **QRE**

Internal and External events

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ASSESSMENT

IN FLORIDA, PHARMACISTS ARE REQUIRED TO DOCUMENT AND EVALUATE QUALITY RELATED EVENTS (**QRE**)

WHICH STATEMENT(S) BEST DESCRIBE A **QRE**?

A) TECHNICIAN REPORTS THAT LEVOFLOXACIN 500 MG TABLETS WERE MIXED IN THE PHARMACY STORAGE CAROUSEL WITH LEVETIRACETAM 500 MG TABLETS

B) ADMINISTRATION OF A MEDICATION TO THE WRONG CLIENT IN A LICENSED HEALTHCARE FACILITY

C) PATIENT RECEIVED A PRESCRIPTION CONTAINER WITH CLONAZEPAM (KLONOPIN®) 1 MG INSTEAD OF THE PRESCRIBED MEDICATION CLONIDINE 0.1 MG

D) PATIENT REPORTED INCIDENCE TO FL DEPARTMENT OF HEALTH THAT A PHYSICIAN REFUSED TO REFILL A ROUTINE MEDICATION

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Mitigating Medication Errors

PROCESS MANAGEMENT

THROUGH

PHARMACY CONTINUOUS QUALITY IMPROVEMENT

https://www.flrules.org/gateway/RuleNo.asp?ID=64B16-27.300

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ISMP TOP 10 ACUTE CARE
RECURRENT MEDICATION ERRORS

1. SELECTING INCORRECT DRUG IN THE DATA SYSTEM/EMR
2. INAPPROPRIATE ORAL METHOTREXATE DOSE
3. LOOK-ALIKE-SOUND-ALIKE DRUG LABELS
4. VERBAL COMMUNICATION ERRORS
5. SAFETY OVERRIDES AUTOMATED DISPENSING CABINETS
6. IV-PUSH MEDICATION ERRORS
7. INCORRECT ADMINISTRATION ROUTE
8. UNSAFE LABELING PREFILLED SYRINGES
9. INCORRECT DOSING OF CYTOTOXIC DRUGS
10. TRACE ELEMENTS IN PARENTERAL NUTRITION

ISMP Medication Safety Alert! Acute Care. January 2020. Accessed 8/12/2023
https://www.ismp.org/acute-care/medication-safety-alert-january-16-2020

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10 MOST COMMON
PRESCRIPTION ERRORS

1. UNCLEAR OR ILLEGIBLE PRESCRIPTIONS
2. INCORRECT DOSAGE OR QUANTITY OF MEDICATION
3. DRUGS THAT INTERACT
4. INCORRECT INSTRUCTIONS (SIG)
5. RATE OF USAGE
6. ERRORS IN DIAGNOSIS AND TREATMENT
7. INACCURATE DRUG NAME
8. INCORRECT PRESCRIPTION FORMAT
9. OMISSION OF PRESCRIPTION
10. PRESCRIPTION OF UNAUTHORIZED DRUGS

https://therapybrands.com/blog/the-10-most-common-prescription-errors/

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RECOGNIZE RECURRING MEDICATION ERRORS

- High risk drugs/process
- Narrow therapeutic index
- Frequently administered drugs
- Sound alike look alike drugs

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HIGH RISK DRUGS

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HIGH RISK PROCESS

- Staffing deficits
- Training gaps
- Unfamiliar tasks
- Workload
- Patient/customer interaction

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NARROW THERAPEUTIC INDEX (NTI)

- Drug related problems are more frequently associated with Narrow therapeutic index (nti) drugs
- ERRORS associated with increased morbidity, mortality and cost
- Small change in dosage could cause adverse effects
- *Study: high proportion of hospitalized patients (35%) RECEIVE NTI-drugs, markedly higher than ambulatory care

*Blix HS, Viktil KK, Moger TA, Reikvam A. *Drugs with narrow therapeutic index as indicators in the risk management of hospitalized patients.* Pharm Pract (Granada). 2010 Jan;8(1):50-5. doi: 10.4321/s1886-36552010000100006. Epub 2010 Mar 15. PMID: 25152793; PMCID: PMC4140577. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4140577/

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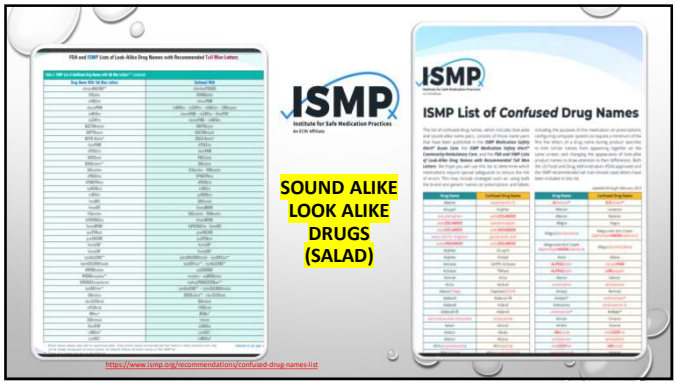
Slide 25

NT0 Anesthesia Syringes
Tomaka, Norman, 2024-05-29T17:47:48.158



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TALLMAN LETTERS

Drug Names	Aware of Confusion? (%)	Add to List? (%)
py**RID**ostigmine and **PHYS**ostigmine	49	91
cyclo**PHOS**phamide (confused with cyclo**SPORINE** and cyclo**SERINE**, already on FDA list)	50	83
dro**PER**idol and dro**NAB**inol	37	82
lina**GLIP**tin and lina**CLO**tide	27	79
le**NALID**omide and le**FLUN**omide	21	79
hydroxy**UREA** (confused with hydr**OXY**zine, already on FDA list)	43	77
dex**AMETH**asone and dexmede**TOMID**ine	44	75
DESMOpressin and **VASO**pressin	44	71
NIZatidine and nita**ZOX**anide	21	68
metho**TREX**ate (confused with met**OL**azone, meth**IMA**zole, and methazol**AMIDE**, already on ISMP list)	31	63

2023 ISMP™

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SOUND ALIKE LOOK ALIKE DRUGS

- Estimated 25% of medication errors
- Drug pairs often implicated in error
- Name similarity (Sound and Text)
- Look alike packaging

https://www.apsf.org/newsletter/june-2023/

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ASSESSMENT

*RECURRENT QUALITY RELATED EVENTS OFTEN INVOLVE **HIGH-RISK** DRUG PRODUCTS*

WHICH STATEMENT(S) BEST DESCRIBE THE POTENTIAL FOR HIGH RISK AND ERROR?

ALL ARE HIGH RISK

A) A PATIENT PRESENTS A PRESCRIPTION FOR ***DIGOXIN 0.25 MG*** PO DAILY. THE PATIENT'S WEIGHT AND AGE LISTED ON THE RX ARE INCORRECT.

B) THE HOSPITAL PHARMACY RECEIVES AN ORDER FOR ***HEPARIN INFUSION*** ON A NEWLY ADMITTED PATIENT. THERE ARE NO "HOME" MEDICATIONS DOCUMENTED

C) PATIENT'S REPRESENTATIVE TELEPHONES THE PHARMACY ASKING FOR A REFILL FOR INSULIN. THERE ARE TWO RXS LISTED: ***HUMALOG®R*** AND ***NOVOLIN®70/30*** IN THE CHART.

D) YOU THE PHARMACIST RECEIVE AN RX FOR ***EXTEMPORANEOUS COMPOUNDED CREAM*** WITH DRUGS YOU ARE NOT FAMILIAR WITH.

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MANAGING NEGATIVE QUALITY RELATED EVENTS

- LISTEN TO THE PATIENT OR PATIENT'S CAREGIVER
- ASSUME THAT AN ERROR HAS OCCURRED
- INVESTIGATE THE FACTS SURROUNDING THE EVENT
- SHOW GENUINE CONCERN FOR THE PATIENT
- APOLOGIZE FOR THE INCONVENIENCE BUT USE JUDGMENT ON ACCEPTING FULL RESPONSIBILITY
- DOCUMENT THE EVENT IMMEDIATELY
- NOTIFY SUPERVISOR/MANAGER/OWNER
- **IF ITS BROKEN, FIX IT & DOCUMENT THE REPAIR**

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DOCUMENTING THE QRE

- DESCRIBE THE QRE
- DATE & TIME WHEN QRE OCCURRED
- DATE AND TIME QRE WAS REPORTED
- HOW THE QRE WAS DISCOVERED
- WAS TREATING PHYSICIAN OR OTHER PROVIDER NOTIFIED?
- PATIENT/CAREGIVER ATTITUDE
- PHYSICIAN/PRESCRIBER ATTITUDE
- IF DISPENSING ERROR OCCURRED, WAS THE CONTAINER RETRIEVED?
- HOW MUCH OF THE DRUG DID THE PATIENT USE/TAKE?
- WHO WERE THE STAFF/CAREGIVER(S) INVOLVED?
- WHAT IS THE STATUS OF THE PATIENT?

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ASSESSMENT

YOU HAVE JUST DOCUMENTED A QRE.

YOU DESCRIBED THE EVENT, INCLUDING STAFFING LEVELS, WORKFLOW ANALYSIS AND DESCRIPTION OF THE TECHNOLOGICAL SUPPORT AT THE TIME OF THE EVENT

- WHO IS GOING TO HAVE ACCESS TO DOCUMENTS GENERATED THROUGH THE CQI PROGRAM?
- CAN THESE DOCUMENTS BE USED AGAINST YOU?

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- WHO IS GOING TO HAVE ACCESS TO DOCUMENTS GENERATED THROUGH THE CQI PROGRAM?
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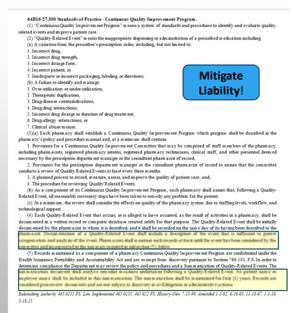
QRE DOCUMENTATION

- **OMIT** PATIENT NAME
- **OMIT** ALL PATIENT IDENTIFIERS
- **OMIT** NAMES OF PATIENT PROVIDERS
- **OMIT** NAMES OF PHARMACY PERSONNEL
- **OMIT** STATUS OF MALPRACTICE REPORT OR SETTLEMENT



64B16-27.300 Standards of Practice - Continuous Quality Improvement Program.

(1) "Continuous Quality Improvement Program" means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

(2) "Quality-Related Event" means the inappropriate dispensing or administration of a prescribed medication including:

(a) A variation from the prescriber's prescription order, including, but not limited to:

1. Incorrect drug,
2. Incorrect drug strength,
3. Incorrect dosage form,
4. Incorrect patient, or
5. Inadequate or incorrect packaging, labeling, or directions.

(b) A failure to identify and manage:

1. Over-utilization or under-utilization,
2. Therapeutic duplication,
3. Drug-disease contraindications,
4. Drug-drug interactions,
5. Incorrect drug dosage or duration of drug treatment,
6. Drug-allergy interactions, or
7. Clinical abuse/misuse.

(3)(a) Each pharmacy shall establish a Continuous Quality Improvement Program which program shall be described in the pharmacy's policy and procedure manual and, at a minimum shall contain:

1. Provisions for a Continuous Quality Improvement Committee that may be comprised of staff members of the pharmacy, including pharmacists, registered pharmacy interns, registered pharmacy technicians, clerical staff, and other personnel deemed necessary by the prescription department manager or the consultant pharmacist of record,
2. Provisions for the prescription department manager or the consultant pharmacist of record to ensure that the committee conducts a review of Quality Related Events at least every three months.
3. A planned process to record, measure, assess, and improve the quality of patient care; and,
4. The procedure for reviewing Quality Related Events.

(b) As a component of its Continuous Quality Improvement Program, each pharmacy shall assure that, following a Quality-Related Event, all reasonably necessary steps have been taken to remedy any problem for the patient.

(c) At a minimum, the review shall consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.

(4) Each Quality-Related Event that occurs, or is alleged to have occurred, as the result of activities in a pharmacy, shall be documented in a written record or computer database created solely for that purpose. The Quality-Related Event shall be initially documented by the pharmacist to whom it is described, and it shall be recorded on the same day of its having been described to the [illegible]

(5) Records maintained as a component of a pharmacy Continuous Quality Improvement Program are confidential under the Health Insurance Portability and Accountability Act and are exempt from discovery pursuant to Section 766.101, F.S. In order to determine compliance the Department may review the policy and procedures and a Summarization of Quality-Related Events. The [illegible]

Rulemaking Authority 465.0155 FS. Law Implemented 465.0155, 465.022 FS. History–New 7-15-99, Amended 1-2-02, 6-16-03, 11-18-07, 1-1-10, 3-18-15.

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QRE DATA

QRE SHOULD BE CONSIDERED CONFIDENTIAL

- DATE/TIME
- LOCATION
- REPORTING STAFF MEMBER
- TYPE OF QRE
  - INCORRECT DRUG
  - DRUG STRENGTH
  - DOSAGE FORM
  - INCORRECT PATIENT
  - OVER/UNDER UTILIZATION
  - INTERACTION
  - THERAPEUTIC DUPLICATION
  - ALLERGY

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QRE DATA

QRE SHOULD BE CONSIDERED CONFIDENTIAL

- LEVEL OF WORKLOAD
- TURNAROUND TIME
- FREQUENCY OF INTERRUPTIONS
- CONSULTATION REQUESTS
- ENVIRONMENT
  - LIGHTING, NOISE, DISTRACTIONS
- INTERPRETATION
  - TRANSCRIPTION ERROR
  - LOOK ALIKE-SOUND ALIKE DRUGS
- OTHER ENVIRONMENTAL FACTORS INVOLVED
  - EMR SYSTEM (SOFTWARE), FAX MACHINE, VOICE MAIL, COUNTING MACHINES, IV HOOD

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WHAT IS A POSITIVE QUALITY RELATED EVENT?
DOES A PHARMACIST CREATE ONE?

- **REASON** - TAMPA PHARMACIST UNDER COLLABORATIVE PRACTICE AGREEMENT RECEIVES A PRESCRIPTION REFILL REQUEST FOR A CHOLESTEROL LOWERING DRUG
- **ACTION** – PHARMACIST PERFORMS CHOLESTEROL ANALYSIS AND FINDS THE PATIENT NOT RESPONDING TO CURRENT THERAPY
  - PHARMACIST CONTACTS PHYSICIAN/PROVIDER
- **RESOLUTION** – PHYSICIAN CHANGES MEDICATION
- **OUTCOME** – PATIENT'S CHOLESTEROL LEVELS DROP

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QRE

Near Miss/Good Catch:
A mistake in prescribing, dispensing, or planned medication administration that is detected and corrected through intervention (by another healthcare provider or patient)

Occurs before the patient receives medication

Adverse Drug *Reaction* (ADR):
Unwanted or *harmful side effect* experienced following the administration of a drug or combination of drugs

Suspected to be related to the drug at normal doses

Adverse Drug *Event* (ADE):
Harm experienced by a patient as a result of exposure to a medication

-Agency for Healthcare Research and Quality (AHRQ) and Patient Safety Network (PSNet™) https://ahrq/psnet.gov
-National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP™) https://www.nccmerp.org/

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MEDICATION RELATED
ERROR

HUMAN ERROR

"WE CANNOT CHANGE THE HUMAN CONDITION, BUT WE CAN CHANGE THE CONDITIONS UNDER WHICH HUMANS WORK."

JAMES REASON, *PH.D. (PROFESSOR OF PSYCHOLOGY)*
UNIVERSITY OF MANCHESTER, UK

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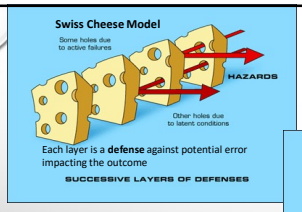
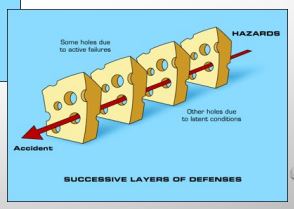


For a catastrophic error to occur, the holes need to align for each step in the process allowing all defenses to be defeated



Reason's "Swiss Cheese Model" of system failure

Every step in a process has the potential for failure, to varying degrees

http://patientsafetyed.duhs.duke.edu/module_a/module_overview.html

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ERROR MITIGATION TOOLS

- **Communicate**
  - CQI meetings
  - In-services
- **Plan for error**
- **Report**
  - Document Event
  - Internal QRE

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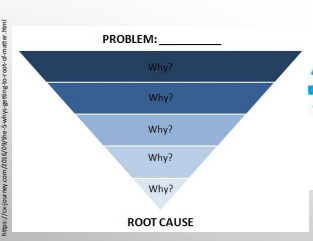
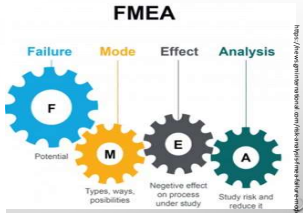
PROBLEM-SOLVING TOOLS

ROOT CAUSE ANALYSIS



FMEA



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https://pharmacist.com/Publications/Pharmacy-Today/Archives

RCA:
Root Cause Analysis
Reactive

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RCA: WHAT IS A ROOT CAUSE ANALYSIS?

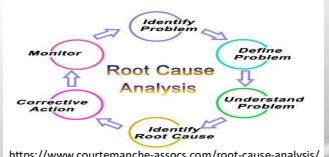
PURPOSE

IDENTIFY SYSTEM VULNERABILITIES AND THE CRITICAL UNDERLYING REASONS FOR **QRE**

- OCCURRENCE
- ADVERSE EVENTS
- NEAR MISSES

GOAL

REDUCE/PREVENT HARM TO PATIENTS



https://www.courtemanche-assocs.com/root-cause-analysis/

48

Conducting a Root Cause Analysis

1. Form a team (stakeholders)
2. Determine the events/Identify breaches of duty
3. Diagram the event
4. Identify the root cause
5. Develop action plan
6. Establish measurable items

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RCA TEAM

- MULTI-DISCIPLINARY
- INQUISITIVE NATURE
- KNOWLEDGEABLE
- DETAIL-ORIENTED
- OBJECTIVE
- STRONG LISTENING SKILLS
- CULTIVATES COOPERATION
- DIVERSE PERSPECTIVE
- PRODUCTIVE
- LOYALTY TO THE ORGANIZATION
- EFFECTIVE COMMUNICATION

https://www.hubgets.com/blog/teamwork-matters-business-success/

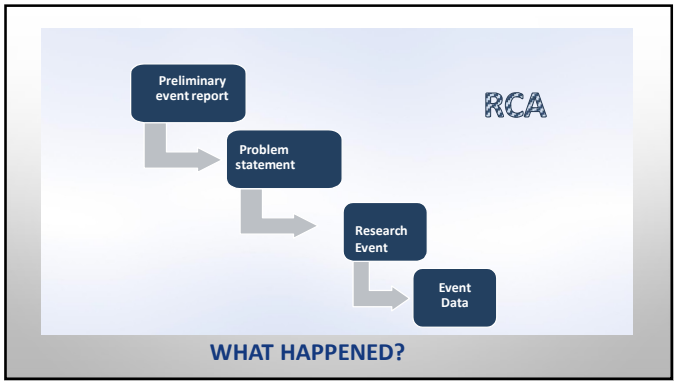
50

RCA MEETING

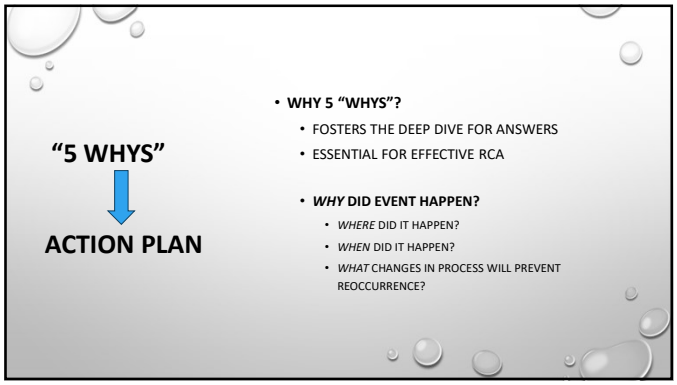
- BEGIN THE MEETING BY INTRODUCING NEW COLLEAGUES OR TEAM MEMBERS BE UNFAMILIAR WITH EACH OTHER
- REMIND THE TEAM OF THE IMPORTANCE OF USING APPROPRIATE VERBIAGE (E.G., "IT APPEARS", "POTENTIALLY", "FROM MY REVIEW")
- ENCOURAGE COMMENTS AND QUESTIONS TO BE DIRECTED TO THE ENTIRE TEAM
- ESTABLISH GOALS FOR THE MEETING (E.G., IDENTIFY ROOT, CLEAR UP DISCREPANCIES, IMPROVE COMMUNICATION)
- CREATE AN ACTION PLAN

Cohen MR, ed. Medication errors. 2nd ed. Washington, DC: American Pharmaceutical Association; 2007.
https://psnet.ahrq.gov/issue/medication-errors-2nd-ed

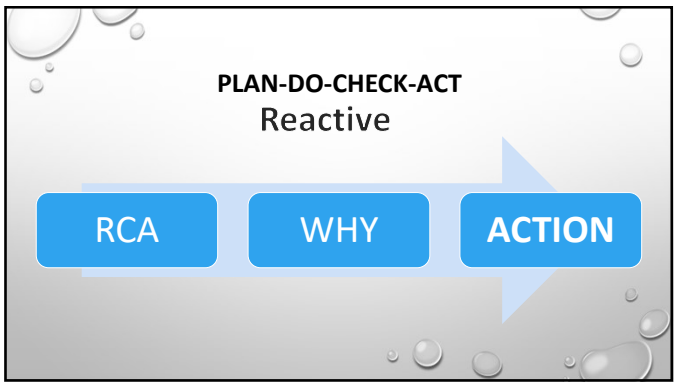
51


Preliminary event report
Problem statement
Research Event
Event Data
RCA
WHAT HAPPENED?

52


"5 WHYS"
ACTION PLAN
• WHY 5 "WHYS"?
• FOSTERS THE DEEP DIVE FOR ANSWERS
• ESSENTIAL FOR EFFECTIVE RCA
• WHY DID EVENT HAPPEN?
• WHERE DID IT HAPPEN?
• WHEN DID IT HAPPEN?
• WHAT CHANGES IN PROCESS WILL PREVENT REOCCURRENCE?

53


PLAN-DO-CHECK-ACT
Reactive
RCA
WHY
ACTION

54

PROACTIVE

https://www.linkedin.com/pulse/fmea-effective-approach-risk-management-shreya-dasgupta

55

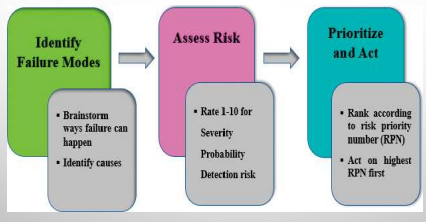
FAILURE MODE EFFECTS ANALYSIS

- **FMEA**
- Purpose: identify system failures of high-risk processes before they occur
- Proactive
- Team-based
- Structured

https://doi.org/10.1186%2Fs12889-021-11369-5

56

FMEA



Serious complex processes priority!

https://pubmed.ncbi.nlm.nih.gov/37260856/

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FMEA Action Plan

Medication Errors Prevention

ACTION PLAN LEADS TO SOLUTIONS

FMEA requires process analysis that may lead to changes

Unique for each risk

Often initiated by documented "Good Catch"

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ASSESSMENT

***QRE** IS OFTEN PREVENTABLE IF THE PROCESS MANAGEMENT IS REVIEWED AND AN ACTION PLAN FOR CHANGE IS ENACTED*

WHICH STATEMENT(S) ARE ACCURATE IN PREVENTING A **QRE**?

A) AFTER A QRE, THE MANAGER SHOULD EVALUATE AND DESIGNATE THE **ROOT CAUSE**

B) ONLY PHARMACISTS ON THE **RCA** TEAM SHOULD FORMULATE AN ACTION PLAN

C) EACH MEMBER OF THE PHARMACY TEAM INVOLVED IN ERROR-PRONE PROCESSES SHOULD BE INVITED TO PARTICIPATE IN **FMEA**

D) ***LESS*** COMPLEX ERROR-PRONE PROCESSES SHOULD BE THE FIRST **FMEA** THE PHARMACY CONDUCTS

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ASSESSMENT

QRE ARE OFTEN PREVENTABLE IF THE PROCESS MANAGEMENT IS REVIEWED AND AN ACTION PLAN FOR CHANGE IS ENACTED.

WHICH STATEMENT(S) ARE ACCURATE IN PREVENTING A QRE?

A) AFTER A QRE, THE MANAGER SHOULD EVALUATE AND DESIGNATE THE ROOT CAUSE

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C) EACH MEMBER OF THE PHARMACY TEAM INVOLVED IN ERROR-PRONE PROCESSES SHOULD BE INVITED TO PARTICIPATE IN FMEA.

D) LESS COMPLEX ERROR-PRONE PROCESSES SHOULD BE THE FIRST FMEA THE PHARMACY CONDUCTS

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CASE STUDY
EXTERNAL
QUALITY RELATED EVENT

- Concentrated potassium chloride was administered IV push to a patient during a cardiac arrest (code)
- **Potassium chloride vials were only stocked in the pharmacy, not on patient care units**
- Restricted access is the effective safeguard to prevent IV administration of concentrated potassium chloride

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CONCENTRATED INJECTION

https://www.pfizerhospitalus.com/products/potassium-chloride-injection

- The event happened when a clinical pharmacist called the central pharmacy to *ask staff to bring a vial of concentrated potassium chloride* to a code he was attending
- Through a series of *miscommunications* and incorrect *assumptions*, the drug was administered undiluted to the patient.

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CONCENTRATED POTASSIUM CHLORIDE

70-year-old intensive care unit (ICU) patient in isolation with a contagious infectious disease (not COVID) experienced a cardiac arrest

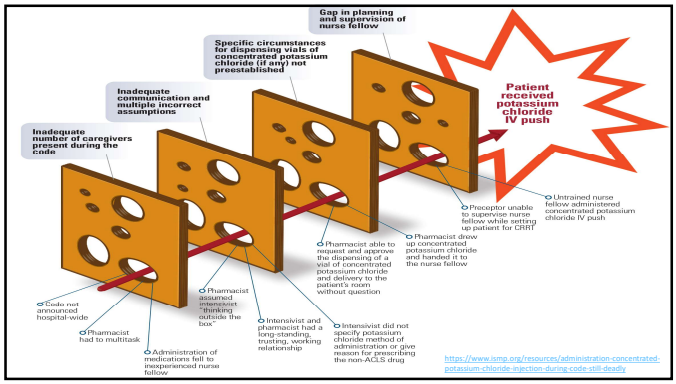
To prevent staff exposure to the infectious disease, the code was not announced hospital-wide but only in the ICU

Small code team—an experienced ICU intensivist, an experienced ICU pharmacist, and a nurse fellow and his preceptor (an experienced ICU nurse)

ICU intensivist verbally requested "potassium chloride 20 mEq IV." The pharmacist, preparing the requested medications, *assumed* the intensivist did not want to administer an infusion, (1 hour administration time)

Agency for Healthcare Research and Quality, https://psnet.ahrq.gov/issue/administration-concentrated-potassium-chloride-injection-during-code-still-deadly

64



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RCA

ROOT CAUSE 1:

AN INADEQUATE NUMBER OF CAREGIVERS WERE PRESENT DURING THE CODE BECAUSE THE CODE WAS NOT ANNOUNCED HOSPITAL-WIDE DUE TO INFECTION CONTROL CONCERNS

ROOT CAUSE 2:

A LACK OF COMMUNICATION AMONG THE CODE TEAM LED TO THE IV PUSH ADMINISTRATION OF THE CONCENTRATED POTASSIUM CHLORIDE

ROOT CAUSE 3:

PHARMACY **DID NOT ESTABLISH CRITERIA** FOR DISPENSING CONCENTRATED POTASSIUM TO A PATIENT CARE UNIT

Administration of Concentrated Potassium Chloride for Injection During a Code: Still Deadly! | Institute For Safe Medication Practices (ismp.org)
https://www.ismp.org/nursing/medication-safety-alert-july-2021

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RCA

ROOT CAUSE 4:

GAP IN TRAINING AND SUPERVISION
LED THE NURSE-FELLOW TO PRACTICE BEYOND SCOPE

ROOT CAUSE 5:

LACK OF STANDARDIZATION:
OVERHEAD ANNOUNCEMENT FOR ALL CODES TO ASSURE EXPERTS ATTEND

Committee to develop an Action Plan

Administration of Concentrated Potassium Chloride for Injection During a Code: Still Deadly! | Institute For Safe Medication Practices (ismp.org)
https://www.ismp.org/nursing/medication-safety-alert-july-2021

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RCA
Action Plan

POTASSIUM CHLORIDE SAFEGUARDS

- DISPENSE VIALS PER ESTABLISHED CRITERIA
- IMPLEMENT A PLAN FOR DILUTE PRE-MIX POTASSIUM CHLORIDE SOLUTIONS ACCESSIBLE IN A CODE
- DO NOT TAKE INJECTABLE POTASSIUM CHLORIDE SAFETY FOR GRANTED, EVEN AFTER YEARS OF NO REPORTED EVENTS
- CLEARLY DESCRIBE SPECIFIC CIRCUMSTANCES WHEN CONCENTRATED POTASSIUM CHLORIDE VIALS MAY BE DISPENSED FROM THE PHARMACY
- ESTABLISH SAFEGUARDS FOR SPECIAL CIRCUMSTANCES TO AVOID ERRORS

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FMEA

PROACTIVE

Risk determination: Same Active questions as in RCA but before an occurrence

Assemble team
Analyze the process
Intensivist-MD, Pharmacist, ICU-Nurse, Nursing assistant, ICU-manager

Brainstorm to identify and predict potential failures

Identify the priority: safe access to high-risk drugs

Implement changes: Action Plan

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FMEA
PROACTIVE

- **HIGH RISK IDENTIFIED**: DRUG ACCESS FOR EMERGENCIES
- **IDENTIFY** POTENTIAL LAPSE THAT COULD CAUSE AN EVENT
  - STAFFING DURING AN UNPLANNED EVENT (CODE)
  - POINT OF CARE: LEVEL OF TRAINING ADDRESSED
  - COMMUNICATION STRATEGY DURING A CODE
  - DRUG PRODUCT ACCESS DEFINED
  - CONSIDER ALTERNATIVES WITH LESS RISK

→ **Serious complex processes priority**!

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FMEA Action Plan: Education
Reducing Medication Errors: Injectable Drugs

1. Pharmacy should dispense ready-to-administer or ready-to-use injectable products in labeled syringes as prescribed for individual patients

2. Commercially available, prefilled syringes of medications that are already labeled should be used when possible

3. Commercially available labels for syringes should be provided and should be routinely restocked in all drug-preparation areas (e.g., ICU, radiology, nuclear medicine).

4. Nurses should be offered the opportunity to assess several label formats and to select one standard format that best meets their needs. Tape is not suitable for labeling syringes

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FMEA Education
Reducing Medication Errors: Injectable Drugs

5. Guidelines should be established for placing the labels on the syringes. Specific directions should be included on how to avoid obstructing the view of gradations on the syringe barrel, contents and functionality

6. Pre-mixed IV Solutions or Syringes preferred in certain clinical areas. (ICU)

7. Staff should not assume that they know what is contained in an unlabeled syringe. All unlabeled syringes should be discarded immediately as a hazardous condition. LABELED Pre-mixed IV or Syringe preferred

8. The staff should reinforce and monitor compliance and should institute a policy mandating that all syringes containing injectable medications be properly labeled.

9. Concentrated high-risk drugs should be restricted but accessible in a premixed labeled dilution, E.g. Infusion bag or syringe.

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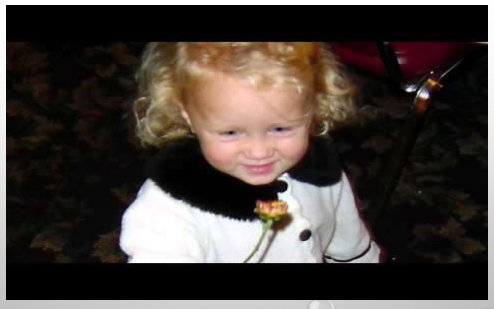
Emily Jerry



https://emilyjerryfoundation.org/

https://www.youtube.com/watch?v=9jmULQ_m04o

73

STANDARD OF CARE IN PHARMACY

- CORRECT PATIENT
- ALLERGIES EVALUATED
- CORRECT DRUG
- CORRECT DOSE
- CORRECT ROUTE
- CORRECT TIME

- DRUG FOOD ANALYSIS
- MOST APPROPRIATE DRUG FOR DIAGNOSIS
  - SOLVES PROBLEM
  - NO ADVERSE EVENT
  - ACCESSIBLE

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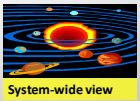
WHAT DO OTHER HEALTH CARE PROVIDERS RECOGNIZE AS THE OUTCOME MEASURE RELATED TO PHARMACY?

MEASURE NEGLIGENCE THROUGH PATIENT CARE OUTCOMES

ERROR FREE PERFORMANCE



System-wide view

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UNDERSTANDING ERRORS

ERROR

FAILURE OF A PLANNED SEQUENCE OF MENTAL OR PHYSICAL ACTIVITIES TO ACHIEVE ITS INTENDED OUTCOME

OR

MISTAKE

(QRE*) THAT REACHES A PATIENT

**Quality related event*

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SLIPS, LAPSES, MISTAKES, VIOLATIONS

- *SLIPS* →ERRORS OF *COMMISSION* WITHOUT INTENT
- *LAPSES* → ERRORS OF *OMISSION* WITHOUT INTENT
- *MISTAKES* →ERRORS OF BOTH TYPES WITHOUT MALICIOUS INTENT
- VIOLATIONS→ ERRORS WITH INTENT

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ALL HUMAN ERRORS ARE NOT EQUAL!

SLIPS ARE OBSERVABLE
REACHED FOR WRONG DRUG BECAUSE OF LABELING

LAPSES ARE NOT OBSERVABLE
COULDN'T REMEMBER WHICH DRUG TO PICK

Mistakes
Actions that proceed *as planned* but fail to achieve its intended outcome because the action was incorrect

Slips
Lapses
Mistakes

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EFFECTIVE MEDICATION ERROR RISK MANAGEMENT

HUMAN ERROR PREVENTION

PROACTIVE ACTIONS MANAGED THROUGH:

- PROCESS AND PROCEDURE CHANGES
- EDUCATION
- DESIGN
- ENVIRONMENT

AVOID behavioral choices that increases risk where risk is not recognized, or is mistakenly believed to be justified

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HUMAN ERROR

- **HUMAN ERROR**
  - WHAT TO DO
  - HOW TO MEASURE IT
  - ERROR RATE
  - NEVER THE "ROOT CAUSE"
- TOOLS
  - PREDICTION OF FAILURE (FMEA)
  - ROOT CAUSE ANALYSIS (REACTIVE)
- TRENDING AND TRACKING
  - OUTCOMES METRICS
  - KEY PERFORMANCE INDICATORS
  - OVERALL EQUIPMENT EFFECTIVENESS
  - SYSTEMATIC PROCESS

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HUMAN ERROR

HUMAN FACTORS ENGINEERING

- FOCUSES ON HOW SYSTEMS WORK IN ACTUAL PRACTICE WITH FALLIBLE HUMAN BEINGS IN CONTROL
- HUMANS ATTEMPT TO DESIGN SYSTEMS THAT OPTIMIZE SAFETY AND MINIMIZE THE RISK OF ERROR IN COMPLEX ENVIRONMENTS

https://psnet.ahrq.gov/primer/human-factors-engineering#Applications-of-Human-Factors-Engineering-to-Improving-Safety

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HUMAN ERROR

HUMAN FACTORS ENGINEERING

- *USABILITY TESTING:* TEST NEW SYSTEMS AND EQUIPMENT UNDER REAL-WORLD CONDITION
- *FORCING FUNCTIONS:* DESIGN THAT PREVENTS AN UNINTENDED ACTIONS FROM BEING PERFORMED
- ALLOWS DESIGN ONLY IF ANOTHER "PROTECTIVE" ACTION IS PERFORMED FIRST

https://psnet.ahrq.gov/primer/human-factors-engineering#Applications-of-Human-Factors-Engineering-to-Improving-Safety

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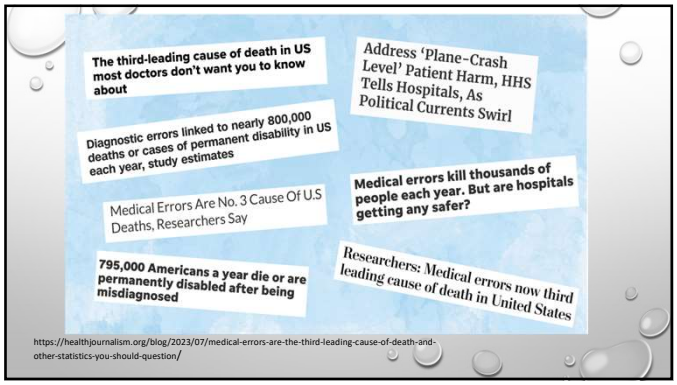


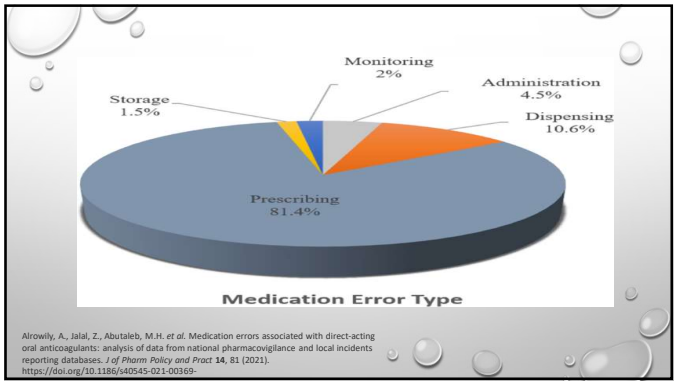
https://healthjournalism.org/blog/2023/07/medical-errors-are-the-third-leading-cause-of-death-and-other-statistics-you-should-question/

83

MEDICATION SAFETY 5 RIGHTS

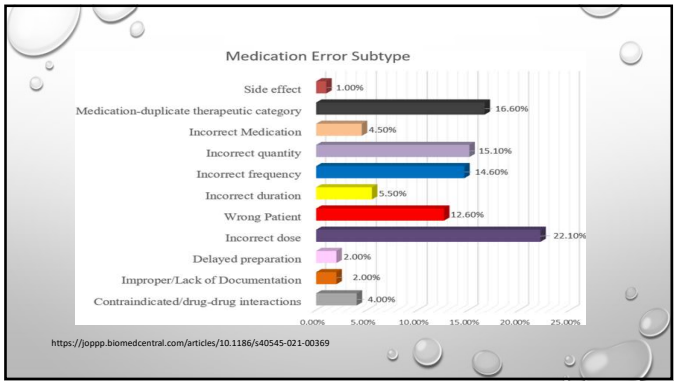
https://www.swisslog-healthcare.com/en-sg/company/blog/5-rights-of-medication

84



Alrowily, A., Jalal, Z., Abutaleb, M.H. *et al.* Medication errors associated with direct-acting oral anticoagulants: analysis of data from national pharmacovigilance and local incidents reporting databases. *J of Pharm Policy and Pract* **14**, 81 (2021). https://doi.org/10.1186/s40545-021-00369-

85



https://joppp.biomedcentral.com/articles/10.1186/s40545-021-00369

86

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https://www.psqh.com/analysis/look-alike-drug-name-errors/

Courtesy of ISMP

88

MEDICATION DISPENSING ERROR

PRESCRIPTION ORDER TRANSMITTED FOR
HYDROXYZINE HCL 10 MG, #24

DIRECTIONS: ONE (1) TABLET EVERY 4 TO 6 HOURS AS NEEDED FOR ITCH. NO REFILL

PRESCRIPTION DISPENSED AND LABELED
HYDRALAZINE HCL 50 MG #24

LOOK ALIKE SOUND ALIKE

- SECOND OCCURRENCE IN THREE MONTHS FOR THIS LOOK-ALIKE DRUG NAME PAIR
- WHY?
- *ROOT CAUSE ANALYSIS* COMPLETED
  - AFTER THE PREVIOUS ERROR: PHARMACY ADDED SHELF LABEL ON EACH PRODUCT LOCATION

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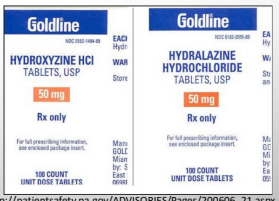
Slips
Lapses
Mistakes

DISPENSING ERROR

DISPENSED THE WRONG DRUG BUT BELIEVED 2 DIFFERENT DRUGS WERE THE SAME MEDICATION

- **LACK OF KNOWLEDGE**
- **LACK OF SAFEGUARDS**
- **ASSESSED INCORRECTLY**
- **DISPENSING ERROR**

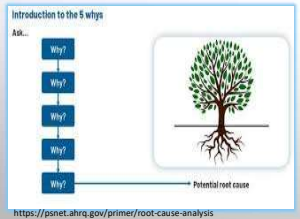


http://patientsafety.pa.gov/ADVISORIES/Pages/200606_21.aspx

90

ROOT CAUSE FAILURE!

TEAM DID NOT PERFORM THE **5 WHYS**



https://psnet.ahrq.gov/primer/root-cause-analysis

PHARMACY TECHNICIAN OBSERVATION:

- SHELF CONFIGURATION 4 X 3' SECTIONS INSTEAD OF 12' ACROSS. LINE OF VISION IMPAIRED!
- BOTH PRODUCTS SAME MANUFACTURER
  - SAME COLOR LABEL
  - SAME FONT
  - TALLMAN LETTERING ALONE INEFFECTIVE

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UPDATED ACTION PLAN

- CONFIGURE PHARMACY SHELVES ACROSS DEPARTMENT TO 12' DIMENSIONS
- ADD "SHELF-TALKER" WITH ALERT: "LOOK ALIKE PRODUCTS"
- PROVIDE STAFF EDUCATION ON TALLMAN LETTERING
- FEEDBACK TO MANUFACTURER REGARDING STRENGTH NOTATION ON LABEL

HydrALAzine vs HydrOXYzine

https://www.pharmacypracticenews.com/PrintArticle/70253

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SUMMARY: DESIGN FOR SAFETY

Design patient care processes to **prevent error**

- **Automate** when appropriate – include use of forcing functions
  Implement TALLman LeTTERing for "look-alikes"
- **Standardize** – reduce reliance on memory
- **Reduce** the number of steps and handoffs (*workflow)*
- Add **redundancy** (double checks) for high risk processes
  (E.g. *every warfarin order dispensed is rechecked*)

http://patientsafetyed.duhs.duke.edu/module_e/basic_safety.html

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QUESTIONS?

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